IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant:	SEIM et al.	Examiner:	Smith, T.
Serial No.:	10/698,858	Group Art Unit:	3762
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Title: ATRIAL ANTITACHYCARDIA PACING MANAGEMENT

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By: Rennae Johnson

APPEAL BRIEF

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Sir:

This Appeal Brief is submitted pursuant to 37 C.F.R. § 41.37 for the above-referenced patent application consistent with the Notice of Appeal filed on August 27, 2007, and the Panel Decision from Pre-Appeal Brief Review to proceed to the Board of Patent Appeals and Interferences dated November 16, 2007.

If necessary, please charge deposit account 50-3581 (GUID.014US01) in the amount of $510.00 for filing this brief in support of an appeal by a large-entity as set forth in 37 C.F.R. § 41.20(b)(2). If necessary, authority is given to charge/credit deposit account 50-3581 (GUID.014US01) additional fees/overages in support of this filing.

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I. REAL PARTY IN INTEREST

The real party in interest is the assignee, Cardiac Pacemakers, Inc.

II. RELATED APPEALS AND INTERFERENCES

Appellant is unaware of any related appeals, interferences or judicial proceedings that would have a bearing on the Board's decision in the instant appeal.

III. STATUS OF CLAIMS

Claims 1-62 remain pending. Each of the pending Claims 1-8, 10-29, and 36-62 has been finally rejected by the Examiner's action dated May 25, 2007, from which Appellant appeals. The pending Claims 1-8, 10-29, and 36-62 under appeal may be found in the attached Claims Appendix. Appellant notes that Claims 9 and 30-35 have not been rejected on any statutory or other proper basis.

IV. STATUS OF AMENDMENTS

No amendments have been presented subsequent to the final rejection dated May 25, 2007.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention relates generally to implantable medical devices and, more particularly, to implantable pacemakers, cardioverter-defibrillators, resynchronizers, and other cardiac stimulation devices that provide atrial antitachycardia pacing management.

Some method embodiments of the present invention are directed to managing atrial antitachycardia pacing (ATP) therapy in response to possible atrial lead dislodgment. (*See, e.g.*, Claim 1, Page 2, Lines 15-20; Fig. 4; among other locations).

Such methods can include measuring an impedance of an atrial lead for a particular patient (*See, e.g.,* Page 11, Lines 9-17; Page 12, Line 28 – Page 13, Line 6; Page 18, Lines 21-26; Page 19, Lines 16-18; element 122 of Fig. 4; elements 204 and 224 of Fig. 6; among other locations). Such methods can further include comparing the measured impedance with an impedance threshold developed for the particular patient. (*See, e.g.,* Page 13, Line 7 – Page 14, Line 26; Page 18, Line 26-28; Page 19, Lines 18-20; elements 124 and 126 of Fig. 4; elements 206, 208, 226, and 228 of Fig. 5; among other locations). Such methods can further include disabling atrial ATP therapy delivery in response to the measured impedance deviating from the impedance threshold by a predetermined factor. (*See, e.g.,* Page 11, Line 5 – Page 12, Line 3; Page 14, Lines 6-26; Page 18, Line 28-30; Page 19, Lines 18-20; element 128 of Fig. 4; element 212 of Fig. 6; among other locations). Such methods may further include that the impedance threshold is characterized by a mean or a median of a plurality of atrial lead impedance measurements. (*See, e.g.,* Claim 4; Page 2, Lines 20-23; Page 12, Line 20-22; among other locations). Such methods may further include that the impedance threshold is characterized by an atrial lead impedance measurement taken immediately before a currently measured impedance (*See, e.g.* Claim 5; Page 12, Lines 22-25; Page 13, Lines 18-20; among other locations). Such methods may further include that the impedance threshold is characterized by at least one atrial lead impedance measurement taken a predetermined amount of time prior to the impedance measurement. (*See, e.g.* Claim 6; Page 13, Lines 20-22; among other locations). Such methods may further include that the predetermined amount of time is about one day. (*See, e.g.,* Claim 7; Page 13, Lines 22-24; among other locations). Such methods may further include that the predetermined amount of time is more than one day. (*See, e.g.,* Claim 8; Page 13, Lines 22-24; among other locations).

Some method embodiments of the present invention are directed to managing atrial antitachycardia pacing (ATP) therapy in response to possible atrial lead dislodgment. (*See, e.g.*, Claim 20; Page 3, Lines 3-23; Page 15, Line 16 – Page 18, Line 26; Fig. 5; among other locations).

Such methods may include measuring an impedance, a capture threshold, and a sense amplitude respectively associated with an atrial lead for a particular patient. (*See, e.g.,* Page 11, Lines 9-17; Page 12, Line 28 – Page 13, Line 6; Page 16, Lines 15-28; Page 18, Lines 21-26; Page 19, Lines 16-18; element 142 of Fig. 5; among other locations). Such methods may further include comparing the impedance, capture threshold, and sense amplitude measurements with impedance, capture threshold, and sense amplitude limits, respectively. (*See, e.g.,* Page 13, Line 7 – Page 14, Line 26; Page 15, Line 28-30; Page 18, Line 26-28; Page 19, Lines 18-20; among other locations). Such methods may further include disabling atrial ATP therapy delivery in response to any of the impedance, capture threshold, and sense amplitude measurements deviating from the impedance, capture threshold, and sense amplitude limits by predetermined impedance, capture threshold, and sense amplitude factors, respectively. (*See, e.g.,* Page 11, Line 5 – Page 12, Line 3; Page 14, Lines 6-26; Page 16, Lines 1-6; Page 18, Line 28-30; Page 19, Lines 18-20; among other locations). Such methods may further include detecting an ambiguity in the impedance, capture threshold, and sense amplitude deviations; and disabling atrial ATP therapy delivery in response to the detected ambiguity. (*See, e.g.,*Claim 21; Page 3, Lines 13-23; Page 16, Lines 25-27; Page 20, Lines 22-25; among other locations). Such methods may further include detecting an ambiguity in the impedance, capture threshold, and sense amplitude deviations; and in response to the detected ambiguity, disabling atrial ATP therapy delivery in response to the measured impedance deviating from the impedance limit by the predetermined factor. (*See, e.g.*, Claim 22; Page 16, Line 25 - Page 17, Line 5; Page 20, Lines 22-25; among other locations). Such methods may further include disabling atrial ATP therapy delivery in response to the measured impedance deviating from the impedance limit by the predetermined factor irrespective of a lack of ambiguity relative to the capture threshold and sense amplitude deviations. (*See, e.g.*, Claim 23; Page 3, Lines 13-23; Page 16, Line 25 - Page 17, Line 5; among other locations). Such methods may further include that one or more of the impedance, capture threshold, and sense amplitude limits are developed from one or more atrial lead measurements taken immediately

before currently made impedance, capture threshold, and sense amplitude measurements. (*See, e.g.*, Claim 28; Page 12, Lines 18-28; Page 13, Lines 14-24; Page 18, Lines 1-7; among other locations). Such methods may further include that one or more of the impedance, capture threshold, and sense amplitude limits are developed from one or more atrial lead measurements taken a predetermined amount of time prior to the respective impedance, capture threshold, and sense amplitude measurements. (*See, e.g.*, Claim 29; Page 12, Lines 18-28; Page 18, Lines 3-8; among other locations).

Some embodiments of the invention are directed to an apparatus for managing atrial antitachycardia pacing (ATP) therapy in response to possible atrial lead dislodgment (*See, e.g.*, Claim 36; Page 3, Line 24 – Page 4, Line 4; Page 5, Line 17 – Page 11, Line 17; the elements of Figs. 1 and 2; among other locations). Such embodiments may include an implantable housing. (*See, e.g.*, Page 6, Line 8-15; element 36 of Figs 1 and 2; among other locations). Such embodiments may further include detection circuitry provided in the housing. (*See, e.g.*, Page 19, Lines 28-30; element 104 of Fig. 2; among other locations). Such embodiments may further include energy delivery circuitry provided in the housing. (*See, e.g.*, Page 19, Lines 28-30; element 106 of Fig. 2; among other locations). Such embodiments may further include a lead system respectively coupled to the detection and energy delivery circuitry, the lead system comprising at least an atrial lead. (*See, e.g.*, Page 5, Line 26 – Page 6, Line 7; Page 7, Line 3 – Page 10, Line 7; Page 19, Line 29-30; elements 24, 26, 110, and 112; among other locations). Such embodiments may further include a control system provided in the housing and coupled to memory within which an impedance threshold developed for a particular patient is stored, the control system measuring an impedance of the atrial lead for the particular patient and comparing the measured impedance with the impedance threshold, the control system disabling atrial ATP therapy delivery in response to the measured impedance deviating from the impedance threshold by a predetermined factor. (*See, e.g.*, Page 20, Lines 1-25; elements 100 and 102 of Fig. 2; elements 122, 124, 126, 128, and 130 of Fig. 4; elements 202, 204, 203, 208, 212 of Fig. 6; among other locations). Such embodiments may further include that the impedance threshold is developed from a single atrial lead impedance measurement. (*See, e.g.*, Claim 37; Page 12, Lines 7-9 and 18-20; Page 13, Lines 14-16; among other locations). Such embodiments may further include that the impedance threshold is developed from a plurality of atrial lead impedance measurements. (*See, e.g.*, Claim 38; Page 2, Lines 20-21; Page 12, Lines

19-20; among other locations). Such embodiments may further include that the impedance threshold is characterized by a mean or a median of a plurality of atrial lead impedance measurements. (*See, e.g.*, Claim 39; Page 2, Lines 20-23; Page 12, Line 20-22; among other locations). Such embodiments may further include that the impedance threshold is characterized by an atrial lead impedance measurement taken immediately before a currently measured impedance. (*See, e.g.*, Claim 40; Page 12, Lines 22-25; Page 13, Lines 18-20; among other locations). Such embodiments may further include that the impedance threshold is characterized by at least one atrial lead impedance measurement taken a predetermined amount of time prior to the measured impedance. (*See, e.g.*, Claim 41; Page 13, Lines 20-22; among other locations). Such embodiments may further include that the predetermined amount of time is about one day prior to a day on which the impedance measurement is taken. (*See, e.g.*, Claim 42; Page 12, Lines 25-28; Page 13, Lines 20-24; among other locations). Such embodiments may further include that the predetermined amount of time is defined by more than one day prior to a day on which the impedance measurement is taken. (*See, e.g.*, Claim 43; Page 12, Lines 25-28; Page 13, Lines 20-24; among other locations). Such embodiments may further include that the control system measures the impedance of the atrial lead by taking a plurality of impedance measurements. (*See, e.g.*, Claim 44; Page 13, Lines 14-16; Page 14, Line 27 – Page 15, Line 4; among other locations). Such embodiments may further include that the control system measures the impedance of the atrial lead by taking a single impedance measurement. (*See, e.g.*, Claim 45; Page 12, Lines 4-20; Page 13, Lines 14-28; among other locations). Such embodiments may further include that the predetermined factor is characterized by a percentage change in the measured impedance relative to the impedance threshold. (*See, e.g.*, Claim 46; Page 2, Lines 23-25; Page 12, Lines 4-9; Page 14, Lines 6-17; Page 18, Lines 6-20; among other locations). Such embodiments may further include that the predetermined factor is characterized by a fixed delta change in the measured impedance relative to the impedance threshold. (*See, e.g.*, Claim 47; Page 2, Lines 23-25; Page 12, Lines 4-9; Page 14, Lines 6-17; Page 18, Lines 6-20; among other locations). Such embodiments may further include that the predetermined factor is characterized by both a percentage change and a fixed delta change in the measured impedance relative to the impedance threshold. (*See, e.g.*, Claim 48; Page 2, Lines 23-25; Page 12, Lines 4-9; Page 14, Lines 6-17; Page 18, Lines 6-20; among other locations). Such embodiments may further include that the control system

measures the impedance using a pace pulse delivered via the atrial lead. (*See, e.g.*, Claim 49; Page 2, Lines 26-30; Page 13, Line 29 – Page 14, Line 5; among other locations). Such embodiments may further include that the control system measures the impedance using a stimulus delivered via the atrial lead, the stimulus having an energy insufficient to effect atrial capture. (*See, e.g.*, Claim 50; Page 2, Lines 26-30; Page 13, Line 29 – Page 14, Line 5; among other locations). Such embodiments may further include that the control system measures the impedance after detection of an atrial arrhythmic event and prior to atrial ATP therapy delivery. (*See, e.g.*, Claim 51; Page 3, Lines 1-2; Page 14, Line 27 – Page 15, Line 4; Page 20, Line 8-13; among other locations). Such embodiments may further include that the control system measures the impedance after an atrial arrhythmic episode is declared and prior to atrial ATP therapy delivery. (*See, e.g.*, Claim 52; Page 3, Lines 1-2; Page 14, Line 27 – Page 15, Line 4; Page 20, Line 8-13; among other locations). Such embodiments may further include that the control system measures the impedance by taking a plurality of impedance measurements after detection of an atrial arrhythmic event and prior to atrial ATP therapy delivery. (*See, e.g.*, Claim 53; Page 3, Lines 1-2; Page 13, Lines 14-16; Page 14, Line 27 – Page 15, Line 4; Page 20, Line 8-13; among other locations). Such embodiments may further include that the control system measures the impedance by taking a plurality of impedance measurements after an atrial arrhythmic episode is declared and prior to atrial ATP therapy delivery. (*See, e.g.*, Claim 54; Page 3, Lines 1-2; Page 13, Lines 14-16; Page 14, Line 27 – Page 15, Line 4; Page 20, Line 8-13; among other locations). Such embodiments may further include that the control system further: measures a capture threshold and a sense amplitude respectively associated with the atrial lead; compares the capture threshold and sense amplitude measurements with capture threshold and sense amplitude limits, respectively; and disables atrial ATP therapy delivery in response to one or more of the impedance measurement deviating from the impedance threshold by a predetermined impedance factor or the capture threshold and sense amplitude measurements deviating from the capture threshold and sense amplitude limits by predetermined capture threshold and sense amplitude factors, respectively. (*See, e.g.*, Claim 55; Page 11, Line 5 – Page 12, Line 3; Page 12, Line 28 – Page 14, Line 26; Page 15, Line 28-30; Page 16, Lines 1-6; Page 16, Lines 15-28; Page 18, Lines 21-30; Page 19, Lines 16-20; elements 142, 144, 146, 148, and 150 of Fig. 5; among other locations). Such embodiments may further include that the control system further: detects an ambiguity in the impedance,

capture threshold, and sense amplitude deviations; and in response to the detected ambiguity, disables atrial ATP therapy delivery. (*See, e.g.*, Claim 56; Page 3, Lines 13-23; Page 16, Lines 25-27; Page 20, Lines 22-25; among other locations). Such embodiments may further include that wherein the control system disables atrial ATP therapy delivery in response to the measured impedance deviating from the impedance threshold by the predetermined factor irrespective of a lack of ambiguity relative to the capture threshold and sense amplitude deviations. (*See, e.g.*, Claim 57; Page 3, Lines 13-23; Page 16, Line 25 - Page 17, Line 5; among other locations). Such embodiments may further include that the control system further: detects an ambiguity in the impedance, capture threshold, and sense amplitude deviations; and in response to the detected ambiguity, disables atrial ATP therapy delivery in response to the measured impedance deviating from the impedance threshold by the predetermined factor. (*See, e.g.*, Claim 58; Page 16, Line 25 - Page 17, Line 5; Page 20, Lines 22-25; among other locations). Such embodiments may further include that the control system, upon detection of an atrial arrhythmia, disables atrial ATP therapy delivery in response to the measured impedance deviating from the impedance threshold by the predetermined factor. (*See, e.g.*, Claim 59; Page 16, Line 25 - Page 17, Line 5; Page 20, Lines 22-25; among other locations). Such embodiments may further include that the control system, upon detection of an atrial arrhythmia, ignores the capture threshold and sense amplitude deviations and disables atrial ATP therapy in response to only the measured impedance deviating from the impedance threshold by the predetermined factor. (*See, e.g.*, Claim 60; Page 17, Lines 24-28; among other locations).

Some embodiments of the invention are directed to a system for managing atrial antitachycardia pacing (ATP) therapy in response to possible atrial lead dislodgment. (*See, e.g.*, Claim 61; Page 3, Line 24 – Page 4, Line 4; Page 5, Line 17 – Page 11, Line 17; the elements of Figs. 1 and 2; among other locations). Such embodiments may include means for measuring an impedance of an atrial lead for a particular patient (*See, e.g.*, Page 5, Line 26 – Page 10, Line 15; Page 11, Lines 9-17; Page 12, Line 28 – Page 13, Line 6; Page 18, Lines 21-26; Page 19, Lines 16-18; Page 19, Line 25 – Page 20, Line 25; elements 20, 22, 24, 26, 36, 38, 40, 42, 44, 46, 48, 50, 54, 56, 58, 60, 62, 64, and 66 of Fig. 1; elements 110, 112, 104, 100, and 102 of Fig. 2; including but not limited to atrial leads, epicardial leads, endocardial leads, patches, ancillary leads, housing electrodes, case electrodes, header electrodes, ventricular leads,

endocardial pacing leads, cardioversion/defibrillation leads; transvenous pacing/defibrillation leads, sensing circuitry, and measuring circuitry; among other disclosed structure). Such embodiments may further include means for comparing the measured impedance with an impedance threshold developed for the particular patient (*See, e.g.*, Page 13, Line 7 – Page 14, Line 26; Page 18, Line 26-28; Page 19, Lines 18-20; Page 19, Line 25 – Page 20, Line 25; elements 102, 100, 104, 108, 114, and 106 of Fig. 2; among other disclosed structure). Such embodiments may further include means for disabling atrial ATP therapy delivery in response to the measured impedance deviating from the impedance threshold by a predetermined factor. (*See, e.g.*, Page 11, Line 5 – Page 12, Line 3; Page 14, Lines 6-26; Page 18, Line 28-30; Page 19, Lines 18-20; Page 19, Line 25 – Page 20, Line 25; elements 102, 100, 104, 108, 114, and 106 of Fig. 2; among other disclosed structure).

Some embodiments of the invention are directed to a system for managing atrial antitachycardia pacing (ATP) therapy in response to possible atrial lead dislodgment. (*See, e.g.*, Claim 62; Page 3, Lines 3-23; Page 15, Line 16 – Page 18, Line 26; Fig. 5; among other locations). Such embodiments may include means for measuring an impedance associated with an atrial lead for a particular patient. (*See, e.g.*, Page 5, Line 26 – Page 10, Line 15; Page 11, Lines 9-17; Page 12, Line 28 – Page 13, Line 6; Page 16, Lines 15-28; Page 18, Lines 21-26; Page 19, Lines 16-18; Page 19, Line 25 – Page 20, Line 25; elements 20, 22, 24, 26, 36, 38, 40, 42, 44, 46, 48, 50, 54, 56, 58, 60, 62, 64, and 66 of Fig. 1; elements 110, 112, 104, 100, and 102 of Fig. 2; including but not limited to atrial leads, epicardial leads, endocardial leads, patches, ancillary leads, housing electrodes, case electrodes, header electrodes, ventricular leads, endocardial pacing leads, cardioversion/defibrillation leads; transvenous pacing/defibrillation leads, sensing circuitry, and measuring circuitry; among other disclosed structure). Such embodiments may further include means for measuring a capture threshold associated with the atrial lead for the particular patient. (*See, e.g.*, Page 5, Line 26 – Page 10, Line 15; Page 11, Lines 9-17; Page 12, Line 28 – Page 13, Line 6; Page 15, Line 16 – Page 18, Line 26; Page 19, Lines 16-18; Page 19, Line 25 – Page 20, Line 25; elements 20, 22, 24, 26, 36, 38, 40, 42, 44, 46, 48, 50, 54, 56, 58, 60, 62, 64, and 66 of Fig. 1; elements 110, 112, 104, 100, and 102 of Fig. 2; including but not limited to atrial leads, epicardial leads, endocardial leads, patches, ancillary leads, housing electrodes, case electrodes, header electrodes, ventricular leads, endocardial pacing leads, cardioversion/defibrillation leads; transvenous pacing/defibrillation leads, sensing

circuitry, and measuring circuitry; among other disclosed structure). Such embodiments may further include means for measuring a sense amplitude associated with the atrial lead for the particular patient. (*See, e.g.*, Page 5, Line 26 – Page 10, Line 15; Page 11, Lines 9-17; Page 12, Line 28 – Page 13, Line 6; Page 15, Line 16 – Page 18, Line 26; Page 19, Lines 16-18; Page 19, Line 25 – Page 20, Line 25; elements 20, 22, 24, 26, 36, 38, 40, 42, 44, 46, 48, 50, 54, 56, 58, 60, 62, 64, and 66 of Fig. 1; elements 110, 112, 104, 100, and 102 of Fig. 2; including but not limited to atrial leads, epicardial leads, endocardial leads, patches, ancillary leads, housing electrodes, case electrodes, header electrodes, ventricular leads, endocardial pacing leads, cardioversion/defibrillation leads; transvenous pacing/defibrillation leads, sensing circuitry, and measuring circuitry; among other disclosed structure). Such embodiments may further include means for comparing impedance, capture threshold, and sense amplitude measurements with impedance, capture threshold, and sense amplitude limits, respectively. (*See, e.g.*, Page 13, Line 7 – Page 14, Line 26; Page 15, Line 28-30; Page 18, Line 26-28; Page 19, Lines 18-20; Page 19, Line 25 – Page 20, Line 25; elements 102, 100, 104, 108, 114, and 106 of Fig. 2; among other disclosed structure). Such embodiments may further include means for disabling atrial ATP therapy delivery in response to any of the impedance, capture threshold, and sense amplitude measurements deviating from the impedance, capture threshold, and sense amplitude limits by predetermined impedance, capture threshold, and sense amplitude factors, respectively (*See, e.g.*, Page 11, Line 5 – Page 12, Line 3; Page 14, Lines 6-26; Page 16, Lines 1-6; Page 18, Line 28-30; Page 19, Lines 18-20; Page 19, Line 25 – Page 20, Line 25; elements 100, 102, 104, 106, 108, and 114, of Fig. 2; among other disclosed structure).

Appellant notes that a single structure may correspond to multiple "means" limitations. (*See, e.g., Winbond Electronics Corp. v. International Trade Commission*, 4 Fed.Appx. 832, C.A.Fed., 2001).

As required by 37 C.F.R. § 41.37(c)(1)(v), a concise explanation of the subject matter defined in each of the independent claims involved in the appeal is provided herein. Appellant notes that representative subject matter is identified for each of these claims; however, the abundance of supporting subject matter in the application prohibits identifying all textual and diagrammatic references to each claimed recitation. Appellant thus submits that other application subject matter, which supports the claims but is not specifically identified above, may be found elsewhere in the application. Appellant further notes that this summary does not

provide an exhaustive or exclusive view of the present subject matter, and Appellant refers to the appended claims and their legal equivalents for a complete statement of the invention.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Claims 1-3, 10-20, 24-27, 36-39, 44-55, and 59-62 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 7,031,773 to *Levine et al.*

B. Claims 4-8, 21-23, 28-29, 40-43, and 56-58 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 7,031,773 to *Levine et al.*

C. Claims 36-60 stand rejected under 35 U.S.C. §112, ¶2, as being indefinite for failing to particularly point out and distinctly claim the subject matter.

VII. ARGUMENT

Appellant notes that Claims 9 and 30-35 have not be rejected on any statutory or other proper basis. Even so, a notice of allowable subject matter regarding those Claims has not been issued.

In specific regard to Claim 9, Appellant notes that this dependent Claim is not included in any of the statements of rejection. MPEP §707.07(d) indicates that where a claim is refused the word "reject" must be used and the statutory basis for any ground of rejection should be designated by an express reference in the opening sentence of each ground of rejection. While it appears that the Examiner intended to reject dependent Claim 9 upon the same basis as the rejection of Claim 44 (See Page 7 of the Final Office Action Mailed 5/25/2007), such a rejection would be improper for the reasons discussed below in connection with the failure of the asserted *Levine* reference to correspond to the claimed invention. Appellant accordingly submits that any alleged rejection of Claim 9 would be improper and requests that it would be reversed.

A. The rejection under 35 U.S.C. §102(e) of Claims 1-3, 10-19, 20, 24-27, 36-39, 44-55, and 59-62 is improper because Levine fails to teach each of the claimed limitations.

Claims 1-3, 10-19, 20, 24-27, 36-39, 44-55, and 59-62 each stand rejected under 35 U.S.C. §102(e) based upon U.S. Patent No. 7,031,733 to *Levine* (hereinafter "*Levine*").

As will be explained below, *Levine* does not provide any teachings corresponding to any of Appellant's following claimed features:

- Disabling atrial antitachycardia pacing (ATP) therapy in response to a measured impedance deviating from a threshold;
- An impedance threshold developed for a particular patient; and
- Measuring impedance, a capture threshold, and a sense amplitude, respectively associated with an atrial lead and comparing the impedance, capture threshold, and sense amplitude measurements with impedance, capture threshold, and sense amplitude limits, respectively.

The Examiner appears to take the untenable position that switching electrodes during autocapture and continuing with autocapture testing constitutes disabling an ATP therapy; that noting electrode polarity constitutes developing an impedance threshold; and that it is inherent that *Levine's* device compares the cited measured parameters to threshold limits. Appellant respectfully submits that *Levine* does not teach at least these limitations recited in the independent Claims, for the reasons discussed below.

Appellant's independent Claims 1, 20, 36, 61, and 62 each recite, among other features, some variation of disabling atrial antitachycardia pacing (ATP) therapy in response to a measured impedance deviating from a threshold.

Levine discloses an implantable stimulator with multiple electrode configurations. (Abstract). *Levine's* implantable stimulator provides autocapture assessment and lead impedance surveillance. (*Id.*). As discussed by *Levine*, capture of a patient's heart requires delivering enough electrical energy to the heart to cause cardiac tissue to contract, where insufficient energy would not cause the cardiac tissue to contract. (Col. 1, Line 61 – Col. 2, Line 5; Col. 2, Lines 46-51; Col. 10, Lines 15-18).

Levine further discloses autocapture routines, whereby the implanted system periodically and automatically assesses the capture threshold of a patient's heart and then accordingly adjusts the pacing energy parameters. (Col. 2, Lines 26-35). To identify the capture threshold, *Levine's* autocapture routine scans for the threshold by delivering successive pacing pulses while an energy parameter, such as pulse amplitude, is progressively reduced or increased while the implanted system senses for capture or loss of capture. (Col. 2, Line 52 – Col. 3, Line 4; Col. 10, Lines 35-55).

Levine also discloses measuring the impedance for the particular electrode combination being used during the capture threshold tests. (Col. 4, Lines 9-11; Col. 10, Line 64 – Col. 11, Line 7). *Levine* discloses that if during an autocapture test an impedance measurement "falls outside of a predetermined or programmable impedance range," then the electrode configuration will be changed and capture will again be attempted. (Col. 11, Lines 10-31; *see also* Col. 4, Lines 9-17).

Accordingly, *Levine* discloses continuing capture detection with a different electrode combination in response impedance deviation while Appellant's independent Claims recite

disabling ATP therapy. Appellant respectfully submits that *Levine's* continuing capture detection with an updated electrode configuration does not constitute disabling a therapy.

In response to Appellant's contentions, the Examiner stated on pages 2-3 of the Office Action mailed 5/25/2007 that:

> In light of the broadest interpretation of the claimed limitation, it is the Examiner's position that Levine disables ATP as taught in column 11, lines 11-20 when therapy is switched from one electrode configuration (for illustration purposes I will call this configuration A) to a different electrode configuration (configuration B), therapy is disabled on configuration A. Applicant did not claim disabling atrial ATP therapy delivery and not applying therapy elsewhere after the therapy is disable. (Emphasis original).

Appellant respectfully submits that the Examiner is improperly applying the tenants of claim interpretation, leading to an erroneous claim interpretation. For example, the Examiner admits to applying "the broadest interpretation of the claimed limitation," even though claims must be given their broadest reasonable interpretation consistent with the specification. (MPEP § 2111; see *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005)). Appellant respectfully submits that when the claims are properly interpreted they are patentable in view of the teachings of the *Levine* reference.

Independent Claims 1, 20, 36, 61, and 62 each recite some variation of disabling ATP therapy. Because the therapy is disabled, as recited in Appellant's base claims, it necessarily follows that the disabled therapy cannot be applied elsewhere (in its disabled state). Appellant's Claims do not recite disabling only a particular set of electrodes for delivering ATP therapy, as it may appear from the Examiner's interpretation. If the therapy itself is disabled, then it is moot whether another electrode set would be able to deliver the therapy.

Because *Levine* discloses changing from one electrode combination while performing an autocapture test to another electrode combination to continue the autocapture test in response to a sensed impedance deviation, such disclosure necessarily does not teach disabling the autocapture test (let alone an ATP therapy).

Appellant's independent Claims 1, 20, 36, 61, and 62 each recite some variation of disabling ATP therapy in response to a measured impedance deviating from a threshold, which is clearly not taught by *Levine*. Accordingly, *Levine* fails to teach each and every element and limitation of these independent Claims. For at least this reason the anticipation rejection of these claims is in error.

Moreover, Appellant respectfully submits that *Levine* does not disclose disabling ATP therapy in response to a measured impedance deviating from a threshold.

As discussed previously, *Levine* discloses an autocapture technique (Col. 10, Line 64-Col. 11, Line 4), and further discloses switching electrodes during autocapture when a sensed impedance "falls outside of a predetermined or programmable impedance range" (Col. 11, Lines 10-31). *Levine's* disclosure of switching electrodes for autocapture does not constitute disabling ATP therapy.

For example, ATP is a therapy for treating tachycardia, tachycardia being characterized by an abnormally high heart rate. Autocapture, on the other hand, is clearly not a therapy for treating tachycardia. Autocapture, rather, is a procedure for determining pacing parameters for subsequent pacing therapy (i.e., the minimum energy required to effect capture of myocardial tissue). (*See Levine*, Col. 1, Lines 42-44; Col. 1, Line 61 – Col. 2, Line 39; Col. 2, Lines 46-51; and Col. 10, Lines 15-19). Appellant respectfully submits that one of ordinary skill in the art would readily understand that ATP therapy and autocapture are distinct methodologies.

Although *Levine* lists anti-tachycardia pacing amongst other tiered therapies (Col. 8, Lines 51-52), *Levine's* mere mention of anti-tachycardia pacing is unconnected with *Levine's* discussion of switching electrodes during autocapture.

For at least these reasons, Appellant respectfully submits that *Levine's* discussion of changing an electrode combination while performing an autocapture procedure does not constitute a teaching of disabling ATP therapy.

Appellant's independent Claims 1, 20, 36, 61, and 62 each recite some variation of disabling ATP therapy in response to a measured impedance deviating from a threshold, which is clearly not taught by *Levine*. Accordingly, *Levine* fails to teach each and every element and limitation of these independent Claims. For at least this further reason the anticipation rejection of these Claims is in error.

Appellant's independent Claims 1, 36, and 61 each further recite, among other features, some variation of an impedance threshold developed for a particular patient.

Levine discloses "a predetermined or programmable impedance range" that when exceeded indicates a lead failure. (Col. 11, Lines 11-15). *Levine* does not disclose an impedance threshold developed for a particular patient. *Levine* does disclose customizing specified parameters for a particular patient. (Col. 8, Line 65 - Col. 9, Line 7). However, these customizable parameters specified by *Levine* only include parameters for detecting arrhythmia and delivery of a therapy (i.e. pulse amplitude, duration, rate, etc.) and do not include an impedance threshold developed for a particular patient. (*Id.*).

The Examiner maintains in the Final Office Action mailed 5/25/2007 that *Levine* does disclose an impedance threshold developed for a particular patient. (Page 3). The Examiner supports this contention by stating "Levine meets this claimed limitation because included in the list of parameters that are developed for the particular patient is electrode polarity which is directly related to the characteristic of an impedance threshold and plays an integral part when measuring impedance as disclosed in the sections cited above [on Page 3 of the Office Action] and as set forth in said claimed limitation." (*Id.*).

Appellant respectfully submits that *Levine's* disclosure of selecting an electrode polarity for a patient does not constitute a teaching of developing an impedance threshold for a particular patient. In contrast to the Examiner's statement that electrode polarity and impedance are directly related, Appellant respectfully submits that one of ordinary skill in the art would understand that an impedance parameter measured between two electrodes may be the same after the electrode polarity is flipped for some configurations, while in other configurations the impedance value may be different upon flipping the electrode polarity. Moreover, implanted pacing electrodes of constant polarity can have different impedance value measurements taken between them over time (i.e., the impedance between two implanted pacing electrodes can change over time even though the respective polarity of the implanted pacing electrodes does not).

Moreover, regardless of whether impedance and polarity are directly related, disclosure of polarity selected for a patient is insufficient to teach an impedance threshold developed for a particular patient. An anticipatory reference requires that the "identical invention must be shown in as complete detail as is contained in the ... claim." (*Richardson v. Suzuki Motor Co.*,

9 USPQ2d 1913, 1920 (Fed. Cir. 1989)). Merely selecting an electrode polarity, which is a binary determination, does not constitute developing an impedance threshold for a particular patient, for at least the reason that the possible values for an impedance threshold are vastly greater in number as compared to binary electrode polarity. Even after the selection of polarity for an electrode combination, the determination of an impedance threshold must still be determined.

As such, Appellant respectfully submits that *Levine's* selection of electrode polarity does not constitute an impedance threshold developed for a particular patient, for at least the reason that these two features are not identical.

Claims 1, 36, and 61 each recite, among other limitations, some variation of an impedance threshold developed for a particular patient, which clearly is not disclosed by *Levine*. Accordingly, *Levine* fails to teach each and every element and limitation of these independent Claims. For at least this further reason the anticipation rejection of these Claims is in error.

Appellant's independent Claims 20 and 62 each further recite, among other features, some variation of measuring impedance, a capture threshold, and a sense amplitude, respectively associated with an atrial lead and comparing the impedance, capture threshold, and sense amplitude measurements with impedance, capture threshold, and sense amplitude limits, respectively.

As discussed above, *Levine* discloses an autocapture technique which enables an impedance measuring circuit "whenever there is a failure to detect an evoked response (presumed loss of capture)." (Col. 11, Lines 1-3). *Levine's* impedance measuring circuit then takes an impedance measurement and compares the measurement to a predetermined range. (Col. 11, Lines 4-15). *Levine* does not teach at least comparing a capture threshold with a capture threshold limit.

In addressing Appellant's position that *Levine* does not teach measuring a capture threshold associated with an atrial lead and comparing the capture threshold with a capture threshold limit, the Examiner states that:

> Not only do the sections pointed to by the Examiner read on said claimed limitations (e.g., column 7, lines 59 and 65; column 10, lines 12-13 and 28-30

and column 10, lines 35-55), but, it is inherent that the device, and many like it in the art, inherently perform said claimed limitations because sense amplifiers coupled with leads and all other associated circuitry of the device have to perform various comparisons and threshold checks on a consistent and regular basis in order to negotiate and execute the various functions and therapies that the device provides. (Final Office Action mailed 5/25/2007, Page 4).

Appellant respectfully submits that the portions of *Levine* cited by the Examiner do not support the Examiner's contention. For example, Column 7, Lines 59 and 65 respectively disclose timing control circuitry 79 and evoked response windows. Column 10, Lines 12-13 and Lines 28-30 respectively discloses detection circuitry for detecting evoked responses and a data acquisition system 90 for measuring the amplitude of a cardiac signal of an evoked response (*See* Col. 10, Lines 18-27). Column 10, Lines 35-55 discloses how autocapture features scan for a capture threshold by delivering successive pacing pulses with decrements in energy level while sensing for evoked responses.

Appellant respectfully submits that the cited portions of *Levine* clearly fail to disclose an embodiment that includes measuring a capture threshold associated with an atrial lead and comparing the capture threshold with a capture threshold limit.

Moreover, Appellant respectfully submits that the recited features of the Claims are not inherently used in *Levine's* device, or others like it, contrary to the Examiner's contention.

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. (*In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art)).

"To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from

a given set of circumstances is not sufficient.'" (*In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)).

The Examiner posits that *Levine's* pacing device inherently performs the recited Claim limitations because such pacing devices measure a capture threshold associated with an atrial lead and then compare the capture threshold with a capture threshold limit. Appellant respectfully submits that the Examiner is impermissibly speculating on what *Levine* might do to account for the absence of relevant teachings present in *Levine*.

The contention that *Levine's* pacing device inherently measures a capture threshold associated with an atrial lead and compares the capture threshold with a capture threshold limit is in error, for at least the reason that *Levine's* pacing device does not necessarily perform these steps. While it is the case that some pacing devices may determine a capture threshold, *Levine's* pacing device need not use a comparison of a measured capture threshold to a capture threshold limit to function in the manner disclosed by *Levine*. Appellant respectfully submits that the Examiner has not explained why *Levine's* device must necessarily compare a measured capture threshold to a capture threshold limit to carry out the disclosed methods.

Appellant respectfully submits that *Levine's* pacing device can operate without a capture threshold limit. (*See* Col. 1, Lines 42-53 of *Levine*, which discusses pacemaker operation that does not appear to require a comparison of a measured capture threshold to a capture threshold limit as recited in Claims 20 and 62).

Accordingly, the features recited in Appellant's independent claims 20 and 62 are not explicitly or inherently present in *Levine's* pacing device, and therefore are not taught by *Levine*.

In light of the above arguments, Appellant respectfully submits that the *Levine* reference does not teach each and every element and limitation of independent Claims 1, 20, 36, 61, and 62. As such, these Claims are not anticipated by *Levine* and the anticipation rejection of these Claims is in error and must be reversed.

For each of the reasons discussed above, Appellant respectfully submits that Claims 1, 20, 36, 61, and 62 recite elements and limitations that are not taught by *Levine's* disclosure. Claims 2, 3, 10-19, 24-27, 37-39, 44-55, 59, and 60 are also patentable over *Levine*, as these Claims respectively depend from independent Claims 1, 20, and 36, which are themselves patentable over *Levine* for the reasons discussed above. Consequently there is an omission of

at least one essential element required for a proper anticipation rejection of independent Claims 1, 20, 36, 61, and 62 and its associated dependent Claims 2, 3, 10-19, 24-27, 37-39, 44-55, 59, and 60, and the anticipation rejection of these Claims should be reversed at least on that basis.

B. The rejection under 35 U.S.C. §103(a) of Claims 4-8, 21-23, 28, 29, 40-43, and 56-58 is improper because Levine fails to teach or suggest each of the claimed limitations.

Claims 4-8, 21-23, 28-29, 40-43, and 56-58 are rejected based on 35 U.S.C. §103(a) as being unpatentable over *Levine*.

Claims 4-8, 21-23, 28-29, 40-43, and 56-58 depend from one of independent Claims 1, 20, and 36. For each of the reasons discussed above, Appellant respectfully submits that independent Claims 1, 20, and 36 are patentable over *Levine*. Accordingly, Claims *4*-8, 21-23, 28-29, 40-43, and 56-58 are also patentable over *Levine*, as these Claims further limit the patentable subject matter of these independent Claims. For at least this reason, the rejection of Claims 4-8, 21-23, 28-29, 40-43, and 56-58 is in error and should be reversed.

Moreover, each of claims dependent Claims 4-8, 21-23, 28, 29, 40-43, and 56-58 further limit some aspect of the impedance limitation from each respective base claim. For example, dependent Claim 4 recites that "the impedance threshold is characterized by a mean or a median of a plurality of atrial lead impedance measurements." The other dependent claims are included in the Claims Appendix portion of this Appeal Brief.

In addressing these dependent claims, the Examiner acknowledges that the claimed limitations are not disclosed by *Levine*. (Part 15 on Page 9 of the Final Office Action mailed 5/25/2007). As such, the Office Action states "however, it is well known in the art to characterize an impedance threshold as set forth in the claim limitations stated herein because they indicate relative displacement of the implanted cardiac lead giving the physician viable information to initiate definitive therapy at the appropriate time." (Id.).

Appellant respectfully disputes that the additional limitations of each of dependent Claims 4-8, 21-23, 28-29, 40-43, and 56-58 are well known, such that the rejection of the claims need not provide a reference which actually provides the requisite teaching or suggestion. Appellant contends that reasonable doubt exists regarding whether each of the limitations of Claims 4-8, 21-23, 28-29, 40-43, and 56-58 are well known. For example,

contrary to the assertion that each of the limitations of dependent Claims 4-8, 21-23, 28-29, 40-43, and 56-58 are well known, the reference relied on by the Examiner itself fails to contemplate these purportedly "well known" facts, as acknowledged in the Office Action.

For this further reason, Appellant respectfully submits that the rejection of Claims 4-8, 21-23, 28-29, 40-43, and 56-58 is in error and must be withdrawn as the rejection fails to provide a requisite teaching or suggestion for each claimed limitation.

C. The rejection under 35 U.S.C. §112, ¶2 of Claims 36-60 is improper because each of these Claims is not indefinite and satisfies 35 U.S.C. §112, ¶2.

Claims 36-60 stand rejected under 35 U.S.C. §112, ¶2, as being indefinite for failing to particularly point out and distinctly claim the subject matter.

Appellant respectfully submits that these Claims are not indefinite as they particularly point out and distinctly claim the inventive subject matter in satisfaction of §112, ¶2.

With regard to these rejections, Appellant notes MPEP § 2173.02, which states that:

> [the Examiner] should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. Examiners are encouraged to suggest claim language to applicants to improve the clarity or precision of the language used (emphasis original)

Appellant respectfully submits that Claims 36-60 define patentable subject matter with the requisite reasonable degree of particularity and distinctness and would reasonably apprise one of ordinary skill in the art of the scope of the Claims. (See *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366, 71 USPQ2d 1081, 1089 (Fed. Cir. 2004) ("The requirement to 'distinctly' claim means that the claim must have a meaning discernible to one of ordinary skill in the art when construed according to correct principles....Only when a claim remains insolubly ambiguous without a discernible meaning after all reasonable attempts at construction must a court declare it indefinite.")).

In specific regard to the §112, ¶2 rejection of Claim 36, the Examiner states that the phrase "coupled to memory" is vague and that is it unclear if the memory is positively or functionally recited. (Page 5 of the Final Office Action mailed 5/25/2007). Claim 36 recites, in part, "a control system provided in the housing and coupled to memory within which an impedance threshold developed for a particular patient is stored." Appellant respectfully submits that skilled artisans know that memory is structure, and that a control system coupled to memory is a well understood structural arrangement. As such, this Claim is not "insolubly ambiguous" as it does have "a meaning discernible to one of ordinary skill in the art," as is therefore in compliance with §112, ¶2. (*Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366, 71 USPQ2d 1081, 1089 (Fed. Cir. 2004).

In further regard to the §112, ¶2 rejection of Claim 36, the Examiner states that it is unknown which element provides the atrial therapy referred to in Claim 36. (Page 5 of the Final Office Action mailed 5/25/2007). Claim 36 states:

> An apparatus for managing atrial antitachycardia pacing (ATP) therapy in response to possible atrial lead dislodgment, comprising:
>
> an implantable housing;
>
> detection circuitry provided in the housing;
>
> energy delivery circuitry provided in the housing;
>
> a lead system respectively coupled to the detection and energy delivery circuitry, the lead system comprising at least an atrial lead; and
>
> a control system provided in the housing and coupled to memory within which an impedance threshold developed for a particular patient is stored, the control system measuring an impedance of the atrial lead for the particular patient and comparing the measured impedance with the impedance threshold, the control system disabling atrial ATP therapy delivery in response to the measured impedance deviating from the impedance threshold by a predetermined factor.

Appellant respectfully submits that one of ordinary skill in the art would understand that a combination of the recited elements provides the atrial therapy referred to in Claim 36.

Appellant further notes *In re Larsen*, as noted in MPEP § 2173.05(e), where an Examiner rejected the claim under 35 U.S.C. § 112, ¶2, because the omission from the claim's preamble of a critical element (i.e., a linear member) renders that claim indefinite. (No. 01-1092 (Fed. Cir., 2001) (unpublished)). The court reversed the rejection and stated that the totality of all the limitations of the claim and their interaction with each other must be considered to ascertain the inventor's contribution to the art. (*Id.*). Upon review of the claim in its entirety, the court concluded that the claim at issue apprised one of ordinary skill in the art of its scope and, therefore, served the notice function required by 35 U.S.C. § 112, ¶ 2. (*Id.*).

Although the Examiner's rejections in the present case do not concern the preambles of the Claims, Appellant notes that the same principles of claim interpretation are relevant. Specifically, the totality of all of the limitations of each Claim and the relationships between them apprises one of ordinary skill in the art of the respective scope of each Claim and therefore satisfies § 112, ¶2.

Furthermore, to any extent that one of ordinary skill in the art is unable to reasonably discern the scope of the claims from the face of the claims themselves, MPEP § 2173.02 clearly sanctions reference to clarifying portions of the Specification. Appellant's Specification provides further support for one having ordinary skill in the art to understand Claim 36 and resolve how the ATP therapy is delivered, including but not limited to Page 6, Lines 1-7; Page 6, Line 2 – Page 7, Line 2; Page 7, Lines 14-24; Page 19, Line 25 – Page 20, Line 25 and Fig. 2. Appellant submits that the Specification provides examples of how the various Claim features interact, thus ensuring the Claims to be reasonably definite to one of ordinary skill in the art.

As such, Appellant respectfully submits that Claim 36 particularly points out and distinctly claims inventive subject matter and is not indefinite, thereby satisfying §112, ¶2. Therefore, the rejection of Claim 36 based on §112, ¶2 is improper and should be reversed.

In regard to the §112, ¶2 rejection of Claims 37-39, the Examiner states that the phrase "the impedance threshold . . . lead impedance measurement" is vague and that it is unclear which element is performing the function in each claim. (Page 5 of the Final Office Action mailed 5/25/2007). Also, in regard to the §112, ¶2 rejection of Claims 40-41, the Examiner states that the phrase "the impedance threshold . . . measure impedance" is vague and that it is unclear which element is performing the function in each claim. (*Id.*). In further regard to the

§112, ¶2 rejection of Claims 46-48, the Examiner states that the phrase "the predetermined factor . . . the impedance threshold" is vague and that it is unclear which element is performing the function in each claim. (Id.).

Appellant respectfully submits that one of ordinary skill in the art would understand that a combination of the recited elements of independent Claim 36 measures impedance and stores the predetermined factor and impedance threshold. Moreover, Appellant's Specification provides further support to one having ordinary skill in the art for understanding Claims 37-39, 40-41, and 46-48 and resolving the how impedance is measured, including but not limited to Page 6, Lines 8-15; Page 6, Line 21-Page 7, Line 2; Page 12, Line 4-Page 14, Line 17; Page 17, Lines 19-29; Page 19, Line 25 – Page 20, Line 25 and Fig. 2. Appellant submits that the Specification provides examples of how the various Claim features interact, thus ensuring the Claims to be reasonably definite to one of ordinary skill in the art.

As such, Appellant respectfully submits that Claims 37-41 and 46-48 particularly point out and distinctly claim inventive subject matter and is not indefinite, thereby satisfying §112, ¶2. Therefore, the rejection of Claims 37-41 and 46-48 based on §112, ¶2 is improper and should be reversed.

In regard to the §112, ¶2 rejection of Claim 49, the Examiner states that the phrase "a pace pulse" is vague and that it is unclear what element is providing a pace pulse. (Page 5 of the Final Office Action mailed 5/25/2007). Appellant's Claim 49 recites, in part, "a pace pulse delivered via the atrial lead." Appellant respectfully submits that one of ordinary skill in the art would understand that the pace pulse is provided by a combination of the recited elements of independent Claim 36 and dependent Claim 49, including the atrial lead. Moreover, the Specification provides further support for understanding Claim 49 and the pace pulse, including but not limited to Page 3, Lines 26-27; Page 19, Line 25 – Page 20, Line 25 and Figs. 1 and 2. Appellant submits that the Specification provides examples of how the various Claim features interact, thus ensuring the Claims to be reasonably definite to one of ordinary skill in the art.

As such, Appellant respectfully submits that Claim 49 particularly points out and distinctly claims inventive subject matter and is not indefinite, thereby satisfying §112, ¶2. Therefore, the rejection of Claim 49 based on §112, ¶2 is improper and should be reversed.

In regard to the §112, ¶2 rejection of Claim 50, the Examiner states that the phrase "a stimulus delivered" is vague and that it is unclear what element is providing a stimulus. (Page 5

of the Final Office Action mailed 5/25/2007). Appellant's Claim 50 recites, in part, "a stimulus delivered via the atrial lead." Appellant respectfully submits that one of ordinary skill in the art would understand that the stimulus is provided by a combination of the recited elements of independent Claim 36 and dependent claim 50, including the atrial lead. Moreover, the Specification provides further support for understanding Claim 50 and the stimulus, including but not limited to Page 6, Line 1 – Page 7, Line 2; Page 7, Lines 14-24; Page 13, Line 29 - Page 14, Line 5; Page 19, Line 25 – Page 20, Line 25 and Figs. 1 and 2. Appellant submits that the Specification provides examples of how the various Claim features interact, thus ensuring the Claims to be reasonably definite to one of ordinary skill in the art.

As such, Appellant respectfully submits that Claim 50 particularly points out and distinctly claims inventive subject matter and is not indefinite, thereby satisfying §112, ¶2. Therefore, the rejection of Claim 50 based on §112, ¶2 is improper and should be reversed.

In regard to the §112, ¶2 rejection of Claims 51 and 53, the Examiner states that the phrase "after detection of an atrial arrhythmic event" is vague and that it is unclear what element is providing detection of an atrial arrhythmic event. (Pages 5-6 of the Final Office Action mailed 5/25/2007).

Appellant's Claim 51 recites that "the control system measures the impedance after detection of an atrial arrhythmic event and prior to atrial ATP therapy delivery."

Appellant's Claim 53 recites that "the control system measures the impedance by taking a plurality of impedance measurements after detection of an atrial arrhythmic event and prior to atrial ATP therapy delivery."

Appellant respectfully submits that an atrial arrhythmic event is not something provided by the elements of the Claims, but rather is something to which elements of the Claims are responding. Also, Appellant respectfully submits that one of ordinary skill in the art would understand that detection of an atrial arrhythmic event is provided by a combination of the recited respective elements of dependent Claims 51 and 53 and independent Claim 36. Moreover, the Specification provides further support for understanding Claims 51 and 53 and the detection of an atrial arrhythmic event, including but not limited to Page 6, Line 8 - Page 9, Line 4; Page 18, Lines 31-30; Page 19, Line 25 – Page 20, Line 25 and Figs. 2 and 6. Appellant submits that the Specification provides examples of how the various Claim features interact, thus ensuring the Claims to be reasonably definite to one of ordinary skill in the art.

As such, Appellant respectfully submits that Claims 51 and 53 particularly point out and distinctly claim inventive subject matter and is not indefinite, thereby satisfying §112, ¶2. Therefore, the rejection of Claims 51 and 53 based on §112, ¶2 is improper and should be reversed.

In regard to the §112, ¶2 rejection of Claims 52 and 54, the Examiner states that the phrase "after detection of an atrial arrhythmic episode" is vague and that it is unclear what element is providing an atrial arrhythmic episode. (Pages 5-6 of the Final Office Action mailed 5/25/2007).

Appellant's Claim 52 recites that "the control system measures the impedance after an atrial arrhythmic episode is declared and prior to atrial ATP therapy delivery."

Appellant's Claim 54 recites that "the control system measures the impedance by taking a plurality of impedance measurements after an atrial arrhythmic episode is declared and prior to atrial ATP therapy delivery."

The recitation of an atrial arrhythmic episode in Claims 52 and 54 is not included as an element or as a function within the claim. Rather, one of ordinary skill in the art would understand that an atrial arrhythmic event is something to which elements of the respective claims are responding. Moreover, declaration of an atrial arrhythmic event is provided by a combination of the recited respective elements of dependent Claims 52 and 55 and independent Claim 36. Additionally, the Specification provides further support for understanding Claims 51 and 53 and the declaration of an atrial arrhythmic event, including but not limited to Page 6, Line 8 - Page 9, Line 4; Page 14, Line 27 – Page 15, Line 4; Page 18, Lines 31-30; Page 19, Line 25 – Page 20, Line 25 and Fig. 2 and 6. Appellant submits that the Specification provides examples of how the various Claim features interact, thus ensuring the Claims to be reasonably definite to one of ordinary skill in the art.

As such, Appellant respectfully submits that Claims 52 and 55 particularly point out and distinctly claim inventive subject matter and is not indefinite, thereby satisfying §112, ¶2. Therefore, the rejection of Claims 52 and 54 based on §112, ¶2 is improper and should be reversed.

As such, Appellant submits that Claims 36-60 are in compliance with §112, ¶2 and request reversal of the §112, ¶2 rejections to these Claims.

VIII. CONCLUSION

In view of the above, Appellant respectfully submits that the claimed invention is patentable over the cited reference and that the rejection of Claims 1-8, 10-29, and 36-62 should be reversed. Appellant respectfully requests reversal of the rejection as applied to the appealed Claims and allowance of the entire application.

Authorization to charge the undersigned's deposit account is provided on the cover page of this brief.

Respectfully submitted,

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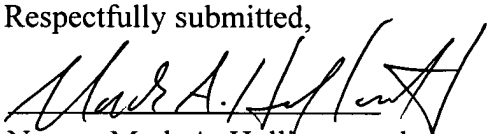

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CLAIMS APPENDIX

1. A method of managing atrial antitachycardia pacing (ATP) therapy in response to possible atrial lead dislodgment, comprising:

measuring an impedance of an atrial lead for a particular patient;

comparing the measured impedance with an impedance threshold developed for the particular patient; and

disabling atrial ATP therapy delivery in response to the measured impedance deviating from the impedance threshold by a predetermined factor.

2. The method according to claim 1, wherein the impedance threshold is developed from a single atrial lead impedance measurement.

3. The method according to claim 1, wherein the impedance threshold is developed from a plurality of atrial lead impedance measurements.

4. The method according to claim 1, wherein the impedance threshold is characterized by a mean or a median of a plurality of atrial lead impedance measurements.

5. The method according to claim 1, wherein the impedance threshold is characterized by an atrial lead impedance measurement taken immediately before a currently measured impedance.

6. The method according to claim 1, wherein the impedance threshold is characterized by at least one atrial lead impedance measurement taken a predetermined amount of time prior to the impedance measurement.

7. The method according to claim 6, wherein the predetermined amount of time is about one day.

8. The method according to claim 6, wherein the predetermined amount of time is more than one day.

9. The method according to claim 1, wherein measuring the impedance of the atrial lead comprises taking a plurality of impedance measurements to characterize the impedance of the atrial lead.

10. The method according to claim 1, wherein measuring the impedance of the atrial lead comprises taking a single impedance measurement to characterize the impedance of the atrial lead.

11. The method according to claim 1, wherein the predetermined factor is characterized by a percentage change in the measured impedance relative to the impedance threshold.

12. The method according to claim 1, wherein the predetermined factor is characterized by a fixed delta change in the measured impedance relative to the impedance threshold.

13. The method according to claim 1, wherein the predetermined factor is characterized by both a percentage change and a fixed delta change in the measured impedance relative to the impedance threshold.

14. The method according to claim 1, wherein measuring the impedance comprises delivering a pace pulse via the atrial lead and deriving the impedance measurement using the delivered pace pulse.

15. The method according to claim 1, wherein measuring the impedance comprises delivering a stimulus via the atrial lead and deriving the impedance measurement using the delivered stimulus, the stimulus having an energy insufficient to effect atrial capture.

16. The method according to claim 1, wherein the impedance is measured after detection of an atrial arrhythmic event and prior to atrial ATP therapy delivery.

17. The method according to claim 1, wherein the impedance is measured after an atrial arrhythmic episode is declared and prior to atrial ATP therapy delivery.

18. The method according to claim 1, wherein measuring the impedance comprises taking a plurality of impedance measurements after detection of an atrial arrhythmic event and prior to atrial ATP therapy delivery.

19. The method according to claim 1, wherein measuring the impedance comprises taking a plurality of impedance measurements after an atrial arrhythmic episode is declared and prior to atrial ATP therapy delivery.

20. A method of managing atrial antitachycardia pacing (ATP) therapy in response to possible atrial lead dislodgment, comprising:

measuring an impedance, a capture threshold, and a sense amplitude respectively associated with an atrial lead for a particular patient;

comparing the impedance, capture threshold, and sense amplitude measurements with impedance, capture threshold, and sense amplitude limits, respectively; and

disabling atrial ATP therapy delivery in response to any of the impedance, capture threshold, and sense amplitude measurements deviating from the impedance, capture threshold, and sense amplitude limits by predetermined impedance, capture threshold, and sense amplitude factors, respectively.

21. The method according to claim 20, further comprising:

detecting an ambiguity in the impedance, capture threshold, and sense amplitude deviations; and

disabling atrial ATP therapy delivery in response to the detected ambiguity.

22. The method according to claim 20, further comprising:

detecting an ambiguity in the impedance, capture threshold, and sense amplitude deviations; and

in response to the detected ambiguity, disabling atrial ATP therapy delivery in response to the measured impedance deviating from the impedance limit by the predetermined factor.

23. The method according to claim 22, further comprising disabling atrial ATP therapy delivery in response to the measured impedance deviating from the impedance limit by the predetermined factor irrespective of a lack of ambiguity relative to the capture threshold and sense amplitude deviations.

24. The method according to claim 20, wherein disabling atrial ATP therapy delivery comprises, upon detection of an atrial arrhythmia, disabling ATP therapy in response to the measured impedance deviating from the impedance limit by the predetermined factor.

25. The method according to claim 20, wherein disabling ATP therapy delivery comprises, upon detection of an atrial arrhythmia, ignoring the capture threshold and sense amplitude deviations, and disabling ATP therapy in response only to the measured impedance deviating from the impedance limit by the predetermined factor.

26. The method according to claim 20, wherein one or more of the impedance, capture threshold, and sense amplitude limits are developed from a single atrial lead measurement.

27. The method according to claim 20, wherein one or more of the impedance, capture threshold, and sense amplitude limits are developed from a plurality of atrial lead measurements.

28. The method according to claim 20, wherein one or more of the impedance, capture threshold, and sense amplitude limits are developed from one or more atrial lead measurements taken immediately before currently made impedance, capture threshold, and sense amplitude measurements.

29. The method according to claim 20, wherein one or more of the impedance, capture threshold, and sense amplitude limits are developed from one or more atrial lead measurements taken a predetermined amount of time prior to the respective impedance, capture threshold, and sense amplitude measurements.

30. The method according to claim 29, wherein the predetermined amount of time is within about one day.

31. The method according to claim 20, wherein the predetermined impedance, capture threshold, and sense amplitude factors are characterized by a percentage change in the impedance, capture threshold, and sense amplitude measurements relative to the impedance, capture threshold, and sense amplitude limits, respectively.

32. The method according to claim 20, wherein the predetermined impedance, capture threshold, and sense amplitude factors are characterized by a fixed delta change in the impedance, capture threshold, and sense amplitude measurements relative to the impedance, capture threshold, and sense amplitude limits, respectively.

33. The method according to claim 20, wherein the predetermined impedance, capture threshold, and sense amplitude factors are characterized by both a percentage change and a fixed delta change in the impedance, capture threshold, and sense amplitude measurements relative to the impedance, capture threshold, and sense amplitude limits, respectively.

34. The method according to claim 20 , wherein the impedance measurement is taken after detection of an atrial arrhythmic event and prior to atrial ATP therapy delivery.

35. The method according to claim 20, wherein the impedance measurement is taken after an atrial arrhythmic episode is declared and prior to atrial ATP therapy delivery.

36. An apparatus for managing atrial antitachycardia pacing (ATP) therapy in response to possible atrial lead dislodgment, comprising:

an implantable housing;

detection circuitry provided in the housing;

energy delivery circuitry provided in the housing;

a lead system respectively coupled to the detection and energy delivery circuitry, the lead system comprising at least an atrial lead; and

a control system provided in the housing and coupled to memory within which an impedance threshold developed for a particular patient is stored, the control system measuring an impedance of the atrial lead for the particular patient and comparing the measured impedance with the impedance threshold, the control system disabling atrial ATP therapy delivery in response to the measured impedance deviating from the impedance threshold by a predetermined factor.

37. The apparatus according to claim 36, wherein the impedance threshold is developed from a single atrial lead impedance measurement.

38. The apparatus according to claim 36, wherein the impedance threshold is developed from a plurality of atrial lead impedance measurements.

39. The apparatus according to claim 36, wherein the impedance threshold is characterized by a mean or a median of a plurality of atrial lead impedance measurements.

40. The apparatus according to claim 36, wherein the impedance threshold is characterized by an atrial lead impedance measurement taken immediately before a currently measured impedance.

41. The apparatus according to claim 36, wherein the impedance threshold is characterized by at least one atrial lead impedance measurement taken a predetermined amount of time prior to the measured impedance.

42. The apparatus according to claim 41, wherein the predetermined amount of time is about one day prior to a day on which the impedance measurement is taken.

43. The apparatus according to claim 41, wherein the predetermined amount of time is defined by more than one day prior to a day on which the impedance measurement is taken.

44. The apparatus according to claim 36, wherein the control system measures the impedance of the atrial lead by taking a plurality of impedance measurements.

45. The apparatus according to claim 36, wherein the control system measures the impedance of the atrial lead by taking a single impedance measurement.

46. The apparatus according to claim 36, wherein the predetermined factor is characterized by a percentage change in the measured impedance relative to the impedance threshold.

47. The apparatus according to claim 36, wherein the predetermined factor is characterized by a fixed delta change in the measured impedance relative to the impedance threshold.

48. The apparatus according to claim 36, wherein the predetermined factor is characterized by both a percentage change and a fixed delta change in the measured impedance relative to the impedance threshold.

49. The apparatus according to claim 36, wherein the control system measures the impedance using a pace pulse delivered via the atrial lead.

50. The apparatus according to claim 36, wherein the control system measures the impedance using a stimulus delivered via the atrial lead, the stimulus having an energy insufficient to effect atrial capture.

51. The apparatus according to claim 36, wherein the control system measures the impedance after detection of an atrial arrhythmic event and prior to atrial ATP therapy delivery.

52. The apparatus according to claim 36, wherein the control system measures the impedance after an atrial arrhythmic episode is declared and prior to atrial ATP therapy delivery.

53. The apparatus according to claim 36, wherein the control system measures the impedance by taking a plurality of impedance measurements after detection of an atrial arrhythmic event and prior to atrial ATP therapy delivery.

54. The apparatus according to claim 36, wherein the control system measures the impedance by taking a plurality of impedance measurements after an atrial arrhythmic episode is declared and prior to atrial ATP therapy delivery.

55. The apparatus according to claim 36, wherein the control system further:

measures a capture threshold and a sense amplitude respectively associated with the atrial lead;

compares the capture threshold and sense amplitude measurements with capture threshold and sense amplitude limits, respectively; and

disables atrial ATP therapy delivery in response to one or more of the impedance measurement deviating from the impedance threshold by a predetermined impedance factor or the capture threshold and sense amplitude measurements deviating from the capture threshold and sense amplitude limits by predetermined capture threshold and sense amplitude factors, respectively.

56. The apparatus according to claim 55, wherein the control system further:

detects an ambiguity in the impedance, capture threshold, and sense amplitude deviations; and

in response to the detected ambiguity, disables atrial ATP therapy delivery.

57. The apparatus according to claim 56, wherein the control system disables atrial ATP therapy delivery in response to the measured impedance deviating from the impedance threshold by the predetermined factor irrespective of a lack of ambiguity relative to the capture threshold and sense amplitude deviations.

58. The apparatus according to claim 55, wherein the control system further:

detects an ambiguity in the impedance, capture threshold, and sense amplitude deviations; and

in response to the detected ambiguity, disables atrial ATP therapy delivery in response to the measured impedance deviating from the impedance threshold by the predetermined factor.

59. The apparatus according to claim 36, wherein the control system, upon detection of an atrial arrhythmia, disables atrial ATP therapy delivery in response to the measured impedance deviating from the impedance threshold by the predetermined factor.

60. The apparatus according to claim 55, wherein the control system, upon detection of an atrial arrhythmia, ignores the capture threshold and sense amplitude deviations and disables atrial ATP therapy in response to only the measured impedance deviating from the impedance threshold by the predetermined factor.

61. A system for managing atrial antitachycardia pacing (ATP) therapy in response to possible atrial lead dislodgment, comprising:

means for measuring an impedance of an atrial lead for a particular patient;

means for comparing the measured impedance with an impedance threshold developed for the particular patient; and

means for disabling atrial ATP therapy delivery in response to the measured impedance deviating from the impedance threshold by a predetermined factor.

62. A system for managing atrial antitachycardia pacing (ATP) therapy in response to possible atrial lead dislodgment, comprising:

means for measuring an impedance associated with an atrial lead for a particular patient;

means for measuring a capture threshold associated with the atrial lead for the particular patient;

means for measuring a sense amplitude associated with the atrial lead for the particular patient;

means for comparing impedance, capture threshold, and sense amplitude measurements with impedance, capture threshold, and sense amplitude limits, respectively; and

means for disabling atrial ATP therapy delivery in response to any of the impedance, capture threshold, and sense amplitude measurements deviating from the impedance, capture threshold, and sense amplitude limits by predetermined impedance, capture threshold, and sense amplitude factors, respectively.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.